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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/529,130  | 06/22/2000  | MICHAEL JOHN DUGGAN  | 1581.0580000        | 2901             |
| 7590  | 10/23/2003  |                      | EXAMINER            |                  |
| STERNE KESSLER GOLDSTEIN & FOX<br>1100 NEW YORK AVENUE NW<br>SUITE 600<br>WASHINGTON, DC 20005-3934 |             |                      | KAM, CHIH MIN       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1653                |                  |

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                                 |                         |
|------------------------|---------------------------------|-------------------------|
| <b>Advisory Action</b> | <b>Applicant No.</b>            | <b>Applicant(s)</b>     |
|                        | 09/529,130                      | DUGGAN ET AL.           |
|                        | <b>Examiner</b><br>Chih-Min Kam | <b>Art Unit</b><br>1653 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a)  The period for reply expires \_\_\_\_ months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 63-70.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,4-12,14,20-41,44-47,50-54 and 57.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The proposed drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10.  Other: The drawings submitted 9/25/03 are approved.

Continuation of 2. NOTE: The response and the amendment to the specification filed September 25, 2003 does not resolve the current issues under 35 USC 103(a). Applicants' response has been fully considered, however, claims 1, 4-12, 14, 20-41, 44-47, 50-54 and 57 remain rejected under 35 USC 103(a).

If applicants' amendment were entered, it would have the following response:

1. Claims 1, 4-12, 14, 20-41, 44-47, 50-54 and 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (WO 96/33273) taken with Sharon et al. (The FASEB Journal 4, 3198-3208 (1990)). Please see paragraph 4 of the previous Office Action mailed July 7, 2003 for the details. In response, applicants indicate the combined references of Foster et al. and Sharon et al. do not establish a *prima facie* case of obviousness because the primary reference, Foster et al., do not disclose the use of a specific lectin such as galactose-binding lectin in preparing the agent, and this deficiency is not cured by the secondary reference, Sharon et al., which merely indicate the information regarding galactose-binding lectins without any suggestion or motivation to the skilled artisan regarding their utilities. Applicant further asserts that unexpected results, e.g., the galactose-binding lectin conjugates of the invention demonstrate superior specificity for pain-sensing cells and hence superior analgesic properties as compared to non-galactose-binding lectin-containing clostridial conjugates have been described in the specification and must be considered by the examiner, and the combination of Foster et al. and Sharon et al. do not teach or suggest the unexpectedly improved targeting specificity for pain-sensing cells that is achieved by the use of galactose-binding lectins in accordance with the applicant's invention (pages 6-15 of the response). The response have been fully considered, however, the argument is not found persuasive because Sharon et al. teach "oligosaccharides such as complexed type oligosaccharides with terminal galactose residues can act as multivalent ligands that cross-link and precipitate galactose or N-acetylgalactosamine specific lectins, and the specificity of interactions of lectins with these multivalent oligosaccharides is greater in the formation of cross-linked complexes than in that of non-cross-linked one, and these results have important implications for the biological functions of cell surface receptors for lectins" (page 3200, right column), which suggests the specific binding of galactose-binding lectins to complexed type galactose-containing oligosaccharides can be implied to the binding of lectin to the cell surface receptors, which is the motivation to use galactose-binding lectins in the agent for targeting receptors on the cell surface. Regarding the specificity of the galactose-binding lectin conjugates toward pain-sensing cells indicated by the applicant, the claims do not cite this limitation, thus, the agents result from the combined references of Foster et al. and Sharon et al. are not different from the claimed compounds. Therefore, the combined teachings of the two references result in the claimed invention.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's response does not resolve current issue under 35 USC 103 (a) .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
October 16, 2003

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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